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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,519	09/29/2003	Takafumi Kurosawa	SHD-002-USA-PCT	9109
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EXAMINER				
MEJCER, MELISSA S				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,519

Applicant(s)

KUROSAWA ET AL.

Examiner

MELISSA S. MERCIER

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Summary

Receipt of Applicants Remarks, Declaration filed under 132, and Amended Claims filed on September 17, 2008 is acknowledged.

Claim Objections

Claims 1 and 3-4 are objected to because of the following informalities: processing is spelled incorrectly in "metal soap processing". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 and 8-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lentini et al. (WO 00/33803) and Katsuhiro (JP01165517) in view of Tanaka (US Patent 5,540,921).

Lentini teaches of the preparation of sunscreen compositions that feel better on the skin and are less irritating than typical sunscreens because the enhanced photo protection is not achieved by using greater quantities of the sunscreen agent, (see page 1, and lines 5-10). "More preferably, the organic sunscreen is octyl methoxycinnamate" and other "sunscreens such as zinc oxide and titanium dioxide" (as specifically recited by Lentini et al. on page 5, lines 22- 23 and lines 10-11, respectively). The organic

sunscreen is present in the amount of 1-10% (page 5, lines 24-26). The total amount of sunscreen is present in the amount of 1-20% and can be a combination of organic and inorganic sunscreens (claims). Therefore, since octyl methoxycinate is disclosed as being present up to 10% of the formulation, the zinc oxide could also be present in the amount up to 10% as well.

Lentini further discloses the use of a fluororesin polymer of a submicron particle size and a sunscreen in a hydrophobic vehicle sunscreen agent", (see page 3, lines 10-12). Lentini additionally teaches the fluororesins can be any fluorinated polymer, (page 4, line 3) and the fluororesin is incorporated into an oil component, (page 4, line 12). Additionally, the fluororesin can be pre-dispersed in hydrocarbon oil (page 4, line 28). These teachings specifically provide and guide the skilled artisan to use "any fluorinated polymer" along with a known sunscreen agent in order to increase the SPF of the sunscreen composition. Moreover, Lentini states that the fluorinated polymer is incorporated or treated with "an oil", "a hydrocarbon oil", or even "a vehicle that is hydrophobic", which provides the skilled artisan not only with explicit teaching of combining or treating any fluorinated polymer with a hydrophobic manner, or hydrophobic medium as specifically disclosed by Lentini. Accordingly, the prior art reference of Lentini provides the skilled artisan with teachings and motivations to use a fluorinated polymer along with the sunscreen agent as well as providing explicit and clear support and suggestions to have this fluorinated polymer occur in a hydrophobic vehicle or environment.

Lentini does not disclose the use of a glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside and a mixture thereof.

Lentini additionally does not disclose the oxide being treated in a hydrophobic manner selected from the group consisting of methyl hydrogen polysiloxane and silane coupling agents, metal soap processing, fluorine processing with perfluoroalkylphosphate diethanolamine salt and perfluoroalkylsilane and processing with dextrin fatty acid esters.

Katsuhiko teaches cosmetic agents that are also used to sustain the effects or prevent the damaging effects of ultraviolet rays of the skin with titanium dioxide particles having a particle size of 100-200nm along with polyoxyethylene methylglycoside in the amount of 3-10%, (see translated Patent Abstract of JP 01165517). In addition, it is well within the knowledge of the skilled artisan to utilize homologues of a compound, such as polyoxyethylene methylglycoside, which would obviously embrace the homologue of polyoxypropylene methylglycoside.

Tanaka discloses a solid O/W-type cosmetic composition comprising a powder component, including titanium dioxide and zinc oxide (column 3, lines 26-35). Powders provided with water repellency by a hydrophobic treatment can also be used. Fluorine compounds, silicone oils, metallic soaps, waxes, oils and fats, hydrocarbons and the like can be given as materials for the hydrophobic treatment (column 3, lines 36-40). Examples 2-3 and Comparative Examples 2-4 use titanium dioxide treated with a fluorine compound disclosed as AG530, which is diethanolamine fluoroalkylphosphate

(column 7, lines 49-54). Example 7 discloses silicone treated micronized titanium dioxide (column 11, lines 23-38). The O/W-type cosmetic composition can be used as solid cosmetic products such as sun screening creams (column 5, lines 25-28).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used to hydrophobic treatment of the oxides disclosed by Tanaka with in the composition of Lentini is order to provide water repellency.

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Since both of these prior art references are directed to the very same use, namely topical sunscreen preparations for the skin, one having ordinary skill in the art would have been motivated to combine sunscreen components that are already known in the prior art to be used to treat the very same condition, namely sunburn.

Response to Arguments

Applicant's arguments filed September 17, 2008 have been fully considered but they are not persuasive.

Applicant argues:

***the instant application does not intend to use fluororesin polymers, such as Teflon, for the purpose of reducing irritation, octylmethoxy cinnamate and ZnO**

can be included in the composition without reducing the amount of each to avoid skin irritation.

While it is conceded the instant application does not require the use of a fluoresein, it is noted that the claims have comprising language, thereby allowing the inclusion of additional components regardless of their material effect on the composition.

***Katsushiro fails to address the issue of irritation caused by octylmethoxy cinnamate with ZnO, or the use of POE methyl glucoside as a component in an external skin preparation containing the same.**

While it is conceded that Katsushiro does not disclose zinc oxide, but rather titanium oxide, it is submitted that zinc oxide and titanium oxide are considered to be functional equivalents of each other as demonstrated by Lentini. Therefore, it would have been obvious to one of ordinary skill to have substituted the titanium oxide of Katsushiro for zinc oxide with the expectation of similar results since both references are drawn to the very same use, namely a topical sunscreen preparation for the skin.

***Tanaka fails to address the issue of skin irritation caused by application of octylmethoxy cinnamate with ZnO.**

Applicant is reminded that the prior art need not address the same problem. Tanaka discloses the advantage of water repellency, therefore, one of ordinary skill in the art would have been motivated to include the hydrophobic treatment of the zinc oxide in order to take utilized the disclosed advantage.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Response to Amendment

The Declaration under 37 CFR 1.132 filed September 17, 2008 is insufficient to overcome the rejection of claims 1-7 based upon Commercial Success as set forth in the last Office action because: the Declaration is unsigned and therefore not a valid declaration. Applicant is directed to MPEP 716.03, which discusses Commercial Success Declarations. Applicant has presented sales numbers, however, Gross sales figures do not show commercial success absent evidence as to market share, or as to what sales would normally be expected in the market. Applicant has not provided any figures as to what the market share of the product is. Applicant has also not demonstrated there is a nexus between the sale of the product and the claimed non-irritating properties. The statement "the product is a product considered as having been successful since the sales of the product have been profitable due at least in part to the skin irritation reduction properties imparted to this product by the claimed combination of components called for in claims 1-3 and 5-12". The examiner has regarded this to be an allegation of why the company views the product successful. Applicant has not provided any evidence or affidavits or testimonials as to the precise nexus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELISSA S. MERCIER** whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615